K081860

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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Daniel J. Williman Specialist, Regulatory Affairs Telephone: (574) 371-8065 Fax: (574) 372-4605
Date:	September 24, 2008
Trade Name:	*Zimmer*® Segmental System Variable Stiffness Stem Extensions and Intercalary Segments
Common Name:	Total Hip Prosthesis
Classification Name and Reference:	Hip joint, metal/ceramic/polymer, semi-constrained, cemented or nonporous uncemented prosthesis. 21 CFR § 888.3353
Predicate Devices:	Zimmer Segmental System, manufactured by Zimmer, Inc. (K070978, cleared July 03, 2007); *MOST* System, manufactured by Intermedics Orthopedics, Inc. (K960626, cleared April 18, 1996 and K973087, cleared November 14, 1997); Orthogenesis LPS System Intercalary, manufactured by DePuy, Inc. (K003182, cleared June 27, 2001)
Device Description:	The Variable Stiffness Stem extensions are intended to be used in the proximal and mid-shaft portion of the femur. They are available in either straight or bowed geometry and are made from *Zimaloy*™ Cobalt-Chromium-Molybdenum Alloy. The Intercalary Segments are intended for the replacement of the mid-shaft portion of the femur or for use as a segment connected to other *Zimmer*® Segmental System components. They are made

from *Tivanium*™ Ti-6Al-4V Alloy.

Intended Use:

General Indications for the Segmental System:

- This device is indicated for:
  - Moderate to severe knee instability
  - Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle
  - Valgus, varus or flexion deformities
  - The salvage of previously failed surgical attempts

Indications specific to the Variable Stiffness Stem extensions:

- Variable Stiffness stem extensions require the use of either a smooth or *Trabecular Metal* stem collar, which must be cemented to the stem. Following cementing to the stem, the smooth collar must be cemented against the bone, but the remainder of the stem must be used uncemented.

Comparison to Predicate Device:

These devices are manufactured, packaged and sterilized using the same materials and processes as the predicate devices. They also have the same intended use and fixation methods as the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:
The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective.

Clinical Performance and Conclusions:
Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

Zimmer, Inc.
c/o Daniel J. Williman
Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K081860
Trade/Device Name: Zimmer Segmental System Variable Stiffness Stem Extensions and Intercalary Segments
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint, metal/ceramic/polymer, semi-constrained, cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: June 30, 2008
Received: July 1, 2008

Dear Mr. Williman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081860

Indications for Use

510(k) Number (if known):

Device Name:

Segmental Variable Stiffness Stems and Intercalary Segments

Indications for Use:

General Indications for the Segmental System:

- This device is indicated for:
  - Moderate to severe knee instability
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number 9/26/08

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)